REMARKS/ARGUMENTS

This amendment is resubmitted in response to the Office Action Summary dated June 20, 2007. A petition for a three month extension of time and authorization to charge the appropriate fee is submitted herewith.

The prior application section has been amended to recite only US 60/428,620. New declarations are submitted herewith listing US60/428,620.

Examiner objected to Figures 3-5 because the y axis recites "ppm Ag in lens". Applicants have amended the description of Figures 3-5 in the specification to more clearly describe the figures. Support for the amendment may be found at page 23, lines 29-30. Applicants submit that the foregoing amendment has traversed the Examiner's rejection. If Examiner disagrees, Applicant requests Examiner provide more detail regarding the to which Examiner objects.

The description of Figure 5 has been further amended to recite the four silver compounds shown in the Figure.

Claim 24 has been amended to depend from claim 23.

Rejections under 35 U.S.C. 112

Examiner has rejected claim 12 as indefinite stating that the phrase "substantially free from visible haze" is not clear. Applicants respectfully disagree. Substantially free from visible haze is defined at page 8, line 33 through page 9, line 2.

Examiner rejected claims 21 and 22. Claim 1 has been amended to recite "at least one silver releasing compound", providing antecedent basis for the term in claims 21 and 22.

Examiner has further rejected claims 26 and 29 as lacking insufficient antecedent basis for the phrase "said reaction mixture". Claims 26 and 29 have been amended to depend from claims 25 and 28 respectively. Applicants respectfully submit that the foregoing arguments and amendments have traversed the rejections based upon 35 U.S.C. 112.

Rejections under 35 U.S.C. 102

Examiner has rejected claims 1, 8-12, 16, 19 and 20 as anticipated by Shimai et al. (JP07-270726A). Shimai et al. discloses a method for injecting contact lenses with silver ions using a specified apparatus. Shimai et al. does not disclose any details of the test used to

evaluate antimicrobial activity, does not disclose how long the antimicrobial efficacy lasts, and contains no data from which release rates could be calculated.

Applicants have amended claim 1 to recite that the ophthalmic device comprises ionized silver in an initial concentration of between about 50 and about 3,000 ppm, in addition to the recited rate constant. Neither the initial ionized silver concentration (which was initially recited in claim 7), nor the release rate constant is disclosed or suggested by Shimai et al.

Examiner has further rejected claims 1, 8-12, 16, 19 23 and 25-30 as anticipated by Christ (US 5,843,186).

Examiner has further rejected claims 1 and 9 as anticipated by Barry et al. (EP10503141) under 35 U.S.C. 102(e).

Examiner has further rejected claims 1, 8-12, 16, 19, 20, 23 and 25-30 as anticipated by Barry et al. under 35 U.S.C. 102(b).

Christ discloses intraocular lenses containing antimicrobial iontophoretic materials. Initial ionized silver concentrations are not disclosed.

Barry et al. discloses antimicrobial ocular lenses containing an metal ions retained on a ceramic carrier. Column 5, lines 35-38. The antimicrobial metal ion is disclosed to be present "in a concentration from about 0.01 to 5 wt% of the zeolite" (col. 8, lines 35-36) and the zeolite is "present in an amount from about 0.1 to about 3% by weight of the polymeric material." Col. 8, lines 42-44. This gives an initial concentration of silver ions of 0.01 ppm to 25 ppm.

Accordingly, neither Barry et al., nor Christ disclose the initial concentrations of ionized silver which are now recited in claim 1. The remaining claims depend directly or indirectly from claim 1. Withdrawal of the rejections under 35 U.S.C. 102 based upon Christ and Barry et al. are respectfully requested.

Rejections under 35 U.S.C. 103

Examiner has further rejected claims 1-35 under 35 U.S.C. 103 as unpatentable over Christ in view of Tanaka et al. (US 4,139,513), Dziabo et al. (US 5,340,583), Maiden et al. (US 6,367,929) or Nissen et al. (Ophthalmologe 2000, Sept. 1997, 640-643).

Tanaka et al. discloses copolymers suitable for use as soft contact lenses. Abstract. Antimicrobial compounds of any kind are neither disclosed nor suggested.

Dziabo et al. discloses contact lenses including "substantially silver-free, substantially non-leachable antimicrobial component." Col. 4, lines 1-2. Antimicrobial components which

release from the contact lens are neither disclosed nor suggested. Applicants respectfully submit that Dziabo et al. teaches away from the present invention. Instead of the silver releasing compounds recited in the present claims Dziabo et al. teaches "substantially silver-free . . . antimicrobial compounds". Instead of the release rates recited in the present claims Dziabo et al. discloses "substantially non-leachable antimicrobial component".

Maiden et al. discloses silicone hydrogels made by including a high molecular weight hydrophilic polymer into the silicone hydrogel monomer mix". Abstract. Antimicrobial compounds are not disclosed or suggested.

Nissen et al. reports the "antimicrobial efficacy of a silver layer on a Weflex 55 hydrogel lens". (Materials and Methods section). Nissen et al. does not disclose the composition of the silver layer or the concentration of silver in the silver layer. Nissen et al. also does not report any data relating to the release of silver ions over time, from which a release constant could be calculated. Finally, Nissen et al. does not report any efficacy data beyond 24 hours.

Claim 1 of the present application recites

> An ophthalmic device comprising a polymer and at least one silver releasing compound in a concentration sufficient to provide ionized silver in an initial concentration of between about 50 and about 3,000 ppm, wherein said ophthalmic device has a haze of less than about 200% and said silver releases from said ophthalmic device during use at rate with a rate constant, calculated using a first order kinetics equation, of up to about 1 $days^{-1}$.

None of the references cited by Examiner disclose or suggest the initial ionized silver concentration recited in claim 1. Examiner has not provided specific reasoning for the rejections of claims 1-14, 16-23 and 25-30. Applicants respectfully submit that without specific reasoning, and because all the references are silent as to the initial ionized silver concentration presently recited in claim 1 (about 50 and about 3,000 ppm), a prima facie case of obviousness has not been made.

Examiner has rejected claim 15 as unpatentable over Dziabo et al. either alone or in view of Tanaka et al. As noted above, Dziabo et al. discloses antimicrobial components which are "substantially silver-free, substantially non-leachable". Col. 4, lines 1-2. Tanaka et al. discloses

copolymers suitable for use as soft contact lenses. Abstract. Antimicrobial compounds of any kind are neither disclosed nor suggested.

Claim 15, depends from claim 1 and recites that the "polymer further comprises a ligand to which said silver is releasably bound." Neither Dziabo et al. nor Tanaka et al. disclose silver releasing compounds of any kind, in any concentration. Applicants respectfully submit claim 15 is patentable over Dziabo et al. taken alone or in combination with Tanaka et al.

Examiner has further rejected claim 24 as unpatentable over Christ either alone or in view of Maiden et al. Christ and Maiden et al. have been discussed above.

Claim 24 depends indirectly from claim 1 and further recites that the contact lens comprises silicone hydrogel is selected from the group consisting of senofilcon A, galyfilcon A, lotrafilcon A and balafilcon A. There is nothing in Christ which suggests that the initial ionized silver concentration and release rates specified in claim 1 could provide ophthalmic devices with the extended silver release and antibacterial efficacy achieved by the present invention. Accordingly, Applicants respectfully submit claim 24 is patentable over the combination of Christ and Maiden et al.

Claims 31-35 have been rejected as unpatentable over Nissen et al. either alone or in view of Maiden et al. Claims 31-35 depend from claim 9 and further recite reductions in antimicrobial colonization. Nissen et al. does not disclose any information relating to the concentration of silver ions released from the lens. Without that information no release constant can be calculated. Moreover, since Nissen et al. provides no details relating to the composition of the silver layer, or the method by which it was applied, it is impossible to repeat Nissen et al. to calculate a release constant. The present invention is concerned with

> "contact lenses that display extended release of silver ions. As used herein extended release means release of silver ions in an amount sufficient to inhibit microbial colonization over an extended period of time, such as two days, preferably seven days, more preferably 14 days and in some cases as many as or more than 30 days. Thus, the present invention allows for the manufacture of ophthalmic devices that

provide resistance to microbial colonization over their entire wear schedule for the ophthalmic device." Page 3, lines 11-13.

There is absolutely no data in Nissen et al. which would suggest that the lenses disclosed therein would be antimicrobial for an extended period of time, and therefore have the release rate constants recited in the present claims. In fact, Nissen et al. does not disclose any efficacy data beyond 24 hours. As discussed above, Maiden et al. does not disclose any antimicrobial compounds at all. According, Applicants submit that claims 31-35 are patentable over Nissen et al. taken alone or in combination with Maiden et al.

Examiner has further rejected claims 1, 5-11, 16, 19, 20, 25 and 28 on the ground of nonstatutory obviousness-type double patenting over claims 27-30, 33-39 and 53 of copending Application No. 10/183,883.

Examiner has further rejected claims 1, 5-11, 16, 19, 20, 26 and 29 on the ground of nonstatutory obviousness-type double patenting over claims 1-4, 18-20, 23,26 and 29-31 of copending Application No. 11/291,462.

Terminal disclaimers are filed herewith. Applicants respectfully submit that the foregoing amendments, arguments and the filing of the terminal disclaimer have traversed the Examiner's rejections. Withdrawal of the rejections is requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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